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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/551,182	09/29/2005	Takashi Ishihara	081356-0251	1844

22428 7590 01/14/2008
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WASHINGTON, DC 20007

EXAMINER

SAUNDERS, DAVID A

ART UNIT	PAPER NUMBER
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1644

MAIL DATE	DELIVERY MODE
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01/14/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/551,182

Applicant(s)

ISHIHARA, TAKASHI

Examiner

David A. Saunders

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-98 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☒ Claim(s) 9-11, 16-19, 24-27, 32-35, 40, 41, 43-47, 52-59, 68-70, 76, 77, 82-84 and 89-98 is/are objected to.
- 8) ☒ Claim(s) See Continuation Sheet are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

Continuation of Disposition of Claims: Claims subject to restriction and/or election requirement are 1-8,12-15,20-23,28-31,36-39,42,48-51,60-67,71-75,78-81 and 85-88.

CLAIMS PENDING

Claims 1-98 are pending

OBJECTION(S) TO CLAIMS

Claims 9-11, 16-19, 24-27, 32-35, 40-41, 43-47, 52-59, 68-70, 76-77, 82-84 and 89-98 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from another multiple dependent claim. See MPEP § 608.01(n). Accordingly, the claims 9-11, 16-19, 24-27, 32-35, 40-41, 43-47, 52-59, 68-70, 76-77, 82-84 and 89-98 not been further considered for restriction.

Claims 1-8, 12-15, 20-23, 28-31, 36-39, 42, 48-51, 60-67, 71-75, 78-81 and 85-88 are subject to restriction as follows:

RESTRICTION GROUPS

Restriction under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1, 6-8 and 48-51, drawn to a method of the use of anion and cation exchange chromatography in the preparation of Immunoglobulins/antibodies.

Group II, claim(s) 2, 4, 6-8, 12, 14-15, 20, 22-23, 28, 30-31, 36, 38-39 and 42, drawn to a method of the use of Protein A Affinity chromatography, then anion and cation exchange chromatography in the preparation of Immunoglobulins/antibodies.

Group III, claim(s) 3, 5-8, 13-15, 21-23, 29-31, 37-39, drawn to a method of the use of Protein A affinity chromatography, then anion and cation exchange chromatography, then hydrophobic chromatography in the preparation of Immunogloblins/antibodies.

Group IV, claim(s) 60-67, 71-75, 78-81 and 85-88, drawn to a method of the use of Protein A Affinity chromatography, in the separation of human and ungulate Immunogloblins/antibodies.

Note that, do to their multiple dependency, certain dependent claims have been included in more than one og Groups I-III.

REASONS INVENTIONS ARE INDEPENDENT OR DISTINCT

The inventions listed as Groups I-IV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Pat 6,281,336 (col. 3, lines 50-53; col. 6, line 54-col. 7, line 31) shows that the use of anion and cation exchangers in series is art known in the preparation of Immunogloblins/antibodies. Therefore Claim 1 of Group I offers no contribution over the prior art, as is required for applicant to have unity of invention.

Furthermore, the IPEA has found that Document 1 (Mollering et al, BioPharma. 1990, 3(1), 34-38) likewise shows the steps of Claim 1 of Group I, in order. Furthermore, Document 1 shows the steps of claim 2 of Group II, in order. The IPEA has found that Document 1, in combination with other documents, would render all of the steps of claim 3 as lacking in an inventive step. There is thus no contribution over the prior art for the first three Groups.

The method of Group IV does not have the same general inventive concept as the method of claim Group I, since the method of Group IV makes use of a Protein A Affinity chromatography step, which is not recited in the method of Group I. While the methods of Group IV and Groups II/III all involve a Protein A Affinity chromatography step, the methods of Groups II/III involve steps that are not practiced in the method of Group IV. Also, the method of Group IV is particularly drawn to the use of Protein A Affinity chromatography in the separation of human and ungulate Immunogloblins/antibodies, while the methods of Groups II/III are silent about the separation of human and ungulate Immunogloblins/antibodies. There is thus no single general inventive concept that unites the method of Group IV with that of any of Groups I-III.

REASONS PROPER AND ADVISORIES TO APPLICANT

Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

- (a) the inventions have acquired a separate status in the art in view of their different classification;
- (b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;
- (c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);
- (d) the prior art applicable to one invention would not likely be applicable to another invention;
- (e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly

and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

CONTACTS

Any inquiry concerning this communication from the examiner should be directed to David A. Saunders, whose telephone number is 571-272-0849. The examiner can normally be reached on Mon.-Thu. from 8:00 am to 5:30 pm and on alternate Fridays.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Typed 1/9/08 DAS

A handwritten signature in black ink, reading "David A. Saunders". The signature is fluid and cursive, with the first letters of each word being capitalized and prominent.

DAVID A. SAUNDERS
PRIMARY EXAMINER